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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,135	09/08/2000	Kazuko Hirabayashi	44342.011800	2368

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT PAPER NUMBER

1635

DATE MAILED: 01/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,135

Applicant(s)

HIRABAYASHI ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 7/17/0 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Final Rejection

Claims 4-11 are pending examination.

Applicants' traversal, cancellation of claims 1-3, and addition of claims 4-11 in paper no. 6 are acknowledged and considered.

Information Disclosure Statement

The information disclosure statement filed 11/21/02 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of an article that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered because the examiner cannot read or speak Russian.

Specification

The objection to the specification is moot in view of the amendment to the specification.

The rejection under 112 enablement for claims 1-3 is moot in view of the cancellation of the claims.

The rejection under 103(a) for claims 1-3 is moot in view of the cancellation of the claims.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wooley et al. (American Journal of Veterinary Research, Vol. 35, pp. 267-73, 1974) taken with Yano et al. (US Patent No. 5,298,614, cited on prior 892) in further view of Yano et al. (EP 0685457A1, IDS). Wooley teaches treating infectious canine hepatitis virus in dogs by administering poly

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I:C to the dogs. Wooley teaches that double stranded polymers of poly I:C have been shown to induce interferon in vitro and in vivo (page 1217). The antiviral activity of poly I:C has been studied in viral infections in man and several animal species. However, Wooley does not specifically teach a method of treating hepatitis in a mammal using a cationic liposome (e.g. 2-O-(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid) with poly I:C, which has a mean length within the range of 100 to 500bp.

However, at the time the invention was made, Yano teaches the poly I: poly C is a substance having a significant activity such as interferon induction action (column 3, lines 32-40). Yano further teaches that when the chain length is limited to certain ranges, the resulting substance exhibit desired physiological activity with markedly less toxicity (column 4, lines 31-39). Yano teaches that experimental techniques have been developed for more accurately determining the molecular weight of macromolecular substances using gel electrophoresis (columns 8 line 61- column 9, line 15). Yano teaches that the fact that the control of molecular size of nucleic acid polymer within a specified range is the primarily important factor for remarkable reduction of toxicity of poly I: poly C and the preferred molecular size for using poly I: poly C is from 100 to 600 base numbers (column 11, lines 13-34). In addition, Yano teaches using a complex (2-O-(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid) to administer double stranded RNA to an individual and that using the lipid reduces toxicity of the double stranded RNA and improves the uptake efficiency of the double stranded RNA into cells ('457, abstract and pages 2-11).

At the time the invention was made it would have been *prima facie* obvious for a person of ordinary skill to use the complex taught by Yano for administering poly I:C, which has a mean

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length within the range of 100 to 500 bp to treat hepatitis in mammals. One of ordinary skill in the art would have been motivated to use 2-O-(2-diethylaminoethyl)carbamoyl-1,3,-O-dioleoylglycerol and a phospholipid with poly I:C for treating hepatitis in a mammal because the lipid reduces toxicity of the double stranded RNA and improves the uptake efficiency of the double stranded RNA into cells of the mammal. In addition, one of ordinary skill in the art would have been motivated to use poly I:C, which has a mean length within the range of 100 to 500bp in the method because this range displays reduce toxicity of the double stranded RNA in a mammal.

In addition, at the time the invention was made it would have been *prima facie* obvious for a person of ordinary skill to use the complex taught by Yano for administering poly I:C, which has a mean length within the range of 100 to 500 bp to treat hepatitis B or C in a mammal. One of ordinary skill in the art would have been motivated to use the complex taught by Yano with poly I:C for treating hepatitis C or B in a mammal because Wooley teaches treating canine hepatitis virus in dogs and that poly I:C has anti-viral activity and hepatitis B and C are viral infections.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

To the extent that the applicants' traversal (See pages 4-5) is applicable to the new rejection set forth above. The traversal is not found persuasive for the reasons set forth above. Furthermore, the applicants traversal states, "Poly I:PolyC is a drug capable of inducing interferons and it is well-known for interferon to be effective in hepatitis and the effective amount is also well-known" (See page 4).

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635
1/10/02

Scott D. Pribe
SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER